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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,049	09/29/2000	Johannes Platzek	SCH-1722	2997

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/672,049

Applicant(s)

PLATZEK ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2002 and 09 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 6-15, 17-22 and 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 16 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-38 are pending. The Amendment filed September 6, 2001, amended claims 1-38. Claims 6-15, 17-22, and 26-38 are withdrawn from consideration, as they are directed to non-elected subject matter.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 9/29/99. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b).

Election/Restrictions

Applicant's election with traverse of Group III, the diamagnetic species of Example 11, and the paramagnetic species of Complex I, wherein R4 is C8F17, L is a direct bond, and M is formula XI, in which Z=Gd, q=1, p=0, in Paper Nos. 7 and 12 is acknowledged. The traversal is on the ground(s) that the subject matter of Groups I to VII, X-XI is directed to a single searchable class. This argument is not persuasive, as Groups I-V and VII-XI are directed to distinct chemical species that differ in chemical structure and nature, as denoted by their distinct classification. However, the Examiner has rejoined Groups I and VI and claims 2-3 for examination as a single invention, as these groups and claims 2-3 are directed toward a single composition.

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A search of Applicant's elected diamagnetic species of Example 11 yielded no results. Thus, claims drawn to such a species would be allowable. The Examiner expanded the search of a diamagnetic species to compounds, wherein R4 is C8F17, L is a disaccharide, and L1 is -CH2-CH2-. The search of Applicant's paramagnetic species was not extended because prior art was found to render the species obvious.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The phrase "paramagnetic and diamagnetic perfluoroalkyl-containing substances" in claims 1-3 is vague and indefinite, as the metes and bounds of the claim are not ascertainable. First, what are the substances that contain these compounds? Second, does "perfluoroalkyl-containing" refer to paramagnetic as well as diamagnetic? Replacing the phrase "containing substances" with the term "compounds" will overcome the first part of this rejection.

(ii) The phrase "which as a central atom" in claim 5 (line 3) is vague and indefinite, as it is confusing. What does "which" refer to?

(iii) The definition of R2 in claim 16 is vague and indefinite, as it is confusing. First, what is ">" referring to on the 3rd line of the definition. Second, what is "optional" and what can R2 be? Third, what is R1?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 16, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Platzek et al. (WO 97/26017) in view of Milius et al. (New J. Chem 1992).

Platzek et al. teach perfluoroalkyl-substituted, paramagnetic metal complexes for use in NMR, X-ray diagnostics, radiodiagnostics, and radiotherapeutic agents. Specifically disclosed is Complex I, Rf-L-M, wherein Rf is C₈F₁₇, L is a direct bond, and M is that of general formula XI of the instant invention when Z₁=Gd, q=1, p=0. The reference lacks diamagnetic perfluoroalkyl-containing substances. See pg. 2-pg. 3; pg. 162-180.

Milius et al. teach perfluoroalkylated anionic sugar phosphodiesteres that are utilized in numerous biomedical applications, such as in vivo oxygen carriers, contrast agents, and drug delivery systems. Disclosed are compounds of formula Rf-L₁-B₂, wherein Rf is C₈F₁₇, L₁ is CH₂CH₂, and B₂ is a disaccharide. See entire disclosure.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the perfluoroalkyl-substituted, paramagnetic metal complexes of Platzek et al. and the perfluoroalkyl anionic sugars of Milius et al. because a) both compounds are disclosed as contrast agents and it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846,

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205 USPQ 1069 (CCPA 1980); b) the compounds of Milius et al. are effective emulsifiers of fluorocarbons and the compounds of Platzek et al. contains fluorocarbons.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 107-117 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant composition as a contrast agent. This is seen to be an expected result based on the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 17, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200